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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,095	11/13/2001	Stephane Bejanin	91.US5.DIV	1774

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,095

Applicant(s)

BEJANIN ET AL.

Examiner

Sheridan L. Swope

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-52 is/are pending in the application.
- 4a) Of the above claim(s) 14-29 and 37-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-36 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/000,489.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0502.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 1652

DETAILED ACTION

Applicant's election, without traverse, of Invention II, Claims 30-36, in the response of July 28, 2004 is acknowledged. Claims 14-52 are pending. Claims 14-29 and 37-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Claims 30-36 are hereby examined.

Specification-Objections

The specification is objected to.

The first paragraph of the specification claims priority to US applications 60/305,456 and 60/302,277. However, the specification fails to claim priority to US applications 60/298,698 or 60/293,574, which are recited as priority documents in the Oath/Declaration. In addition, the relationship of the instant application as a divisional of the parent application, 09/924,340, should be stated. Corrections are required.

The specification, on page 200, lines 30-32, states that plasminute consists of residues 585-790 of plasminogen. Yet, SEQ ID NO: 2 consists of residues 585-791 of the plasminogen sequence taught by both Petersen et al, 1990 and Castellino et al, 1995 (both in IDS). Clarification is required. For purposes of examination, it is assumed that the protein of the instant invention, plasminute, consists of residues 585-791 of the plasminogen taught by Petersen et al and Castellino et al, in which the C-terminal five amino acid residues are -Val-Met-Arg-Asn-Asn.

Art Unit: 1652

GENSET polynucleotides and polypeptides are defined using the term GENSET (pg 8, lines 7-15); however, the specification fails to define the term "GENSET". A definition is required.

Title

The title is objected to for not being descriptive of the instant invention.

Oath/Declaration

The Oath/Declaration of May 1, 2002 is objected to for listing the filing date for application US 60/293,574 incorrectly. The correct filing date for said application is May 25, 2001. A new Oath/Declaration is required.

Abstract

The abstract is objected to. The term "GENSET" should be defined in the abstract. Also, an [and] should be inserted in line 3 of the abstract: "...markers, [and] in...".

Information Disclosure Statement

The US PTO/1449 form of May 1, 2002 is objected to for failing to state the data-base in which the disclosed sequences for Accession No. AAR34428 and Accession No. AAR56472 can be found. Said disclosed sequences cannot be found in either the NCBI or EMBL data-bases under the recited accession numbers. A new US PTO/1449, with a complete reference for said sequences, is required.

Claims-Objections

Claim 30 is objected to for being dependent upon a non-elected claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Art Unit: 1652

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting

It is noted that copending Applications SN# 10/475,075, 10/485,231, and 10/495,300 have the same title and inventors as the instant application. Thus, said copending applications may recite the same or overlapping inventions to those recited herein. Since SN# 10/475,075, 10/485,231, and 10/495,300 are not presently available for review, no determination has been made as to whether or not a double patenting rejection over the claims from SN# 10/475,075, 10/485,231, and 10/495,300 should be applied to the claims of the instant application. If, upon availability of the above applications to the Examiner, it is determined that there are conflicting claims between SN# 10/475,075, 10/485,231, and 10/495,300 and the instant application, double patenting will not be considered as a new grounds of rejection.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 recites a polypeptide fragment of SEQ ID NO: 54 comprising residues 1-207 of SEQ ID NO: 54. However, residues 1-207 is the full-length of SEQ ID NO: 54. The recited polypeptide cannot, simultaneously, be the full-length of SEQ ID NO: 54 and a fragment of SEQ ID NO: 54. Is Applicant's intention to recite a polypeptide consisting of SEQ ID NO: 54 or is Applicant's intention to recite a specific fragment of SEQ ID NO: 54? Clarification is

Art Unit: 1652

required. For purposes of examination, it is assumed that Applicant's intention is to recite a specific, as yet undisclosed, fragment of SEQ ID NO: 54.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

In this regard, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breadth of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 31-33 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 54, does not reasonably provide enablement for any fragment of SEQ ID NO: 54. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Art Unit: 1652

Claims 31, 32, and 36 are so broad as to encompass any fragment of SEQ ID NO: 54.

Claim 33 is so broad as to encompass any fragment of SEQ ID NO: 54 having any biological activity. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of possible functions and activities for the large number of polypeptides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which fragments can be used to obtain the desired function or activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant to deletion and which are conserved (i.e. expectedly intolerant to deletion), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 54.

While recombinant and mutagenesis techniques, as well as an extremely large number of functional assays, are known, it is not routine in the art to screen multiple fragments for any function, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid deletions can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple deletions.

The specification does not support the broad scope of Claims 31, 32, and 36 which, encompasses all polypeptide fragments of SEQ ID NO: 54. The specification does not support the broad scope of Claim 33 which, encompasses all polypeptide fragments of SEQ ID NO: 54.

Art Unit: 1652

having any biological activity. The specification does not support the broad scope of Claims 31-33 and 36 because the specification does not establish: (A) all functions or biological activities for any fragment of SEQ ID NO: 54; (B) regions of the protein structure which may be deleted without effecting any desired function or activity; (C) the general tolerance of the desired function or activity to modification and extent of such tolerance; (D) a rational and predictable scheme for making any fragment with an expectation of obtaining the desired function or activity; and (E) the specification provides insufficient guidance as to which of the large number of possible fragments is likely to be successful for use for an infinite number of possible functions or activities.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of fragments of SEQ ID NO: 54 having an enormous number of possible functions or activities. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 31-33 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

Art Unit: 1652

had possession of the claimed invention. These claims are directed to a genus of polypeptide fragments derived from the protein set forth by SEQ ID NO: 54. The specification does not contain any disclosure of the function of all said polypeptide fragments. The genus of polypeptides that comprise these above fragments is a large variable genus with the potentiality of having many different functions or activities. Therefore, many functionally unrelated polypeptides are encompassed within the scope of these claims, including polypeptides with no function. The specification discloses the function of only a single species of the claimed genus, the protein of SEQ ID NO: 54, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The priority date for the instant application is taken to be June 29, 2001, the filing date of US 60/302,277. Neither US 60/298,698 nor US 60/293,574 disclose the sequence of SEQ ID NO: 54.

Art Unit: 1652

Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Petersen et al or Castellino et al, 1995 (both in the IDS). Both Petersen et al and Castellino et al teach a polypeptide, human plasminogen, comprising SEQ ID NO: 54. Therefore, Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Petersen et al or Castellino et al, 1995.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-36 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aguzzi et al, 2002 (filing date 23-APR-2001). Aguzzi et al teach peptide libraries of human plasminogen fragments linked to beads, displayed on phage, or expressed in host cells ([0035]; [0069]; Example 15, [0157] and [0158]). Said peptides libraries taught by Aguzzi et al would include fragments of the protein set forth by SEQ ID NO: 54, as recited in Claims 31-36. Aguzzi et al do not actually make the human plasminogen fragments taught therein; however, they teach that fragments of human

Art Unit: 1652


plasminogen can be made and used. Furthermore, Aguzzi et al, in teaching that said fragments are useful in determining the parts of plasminogen that bind the PrPSc prion protein, provide motivation for making fragments of plasminogen ([0069]; Example 15; [0157] and [0158]). The expectation of success in making fragments of plasminogen, including fragments of the polypeptide of SEQ ID NO: 54, is high because, as taught by Aguzzi et al, the prior art offers many possibilities to determine and detect certain parts of a protein, using peptide fragments, which are involved in specific binding of the protein to a certain target ([0155]) and, furthermore, making peptide fragments is well known in the art (Elkon et al, 1992). Therefore, 31-36 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aguzzi et al, 2002.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.


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